

## **REMARKS**

Of the 21 original claims pending in this application, claims 1, 12, 51, 54 and 56-57 are amended. Claims 6, 53 and 55 have been cancelled. With this response, claims 1-2, 5, 7-12, 15-18, 51-52, 54, and 56-57 are now pending.

The Specification has been amended herewith. Firstly, the Specification has been further amended to provide proper antecedent basis for the claimed subject matter in claims 17 and 18. Specifically, literal support for the aspects that the loading of the catheter into the epidural dispenser system of the present invention can be performed manually, mechanically, or through an automated basis has been added on page 11 of the specification as originally filed. Additionally, a replacement Abstract has been included which is limited in length to not exceed 150 words, so as to bring the Abstract into compliance with 37 C.F.R. § 1.72. In both instances, Applicant contends that no new matter was added with these amendments, for the subject matter added to the specification was claimed in the application as originally filed and so constitutes a clear disclosure of the subject matter (see, MPEP § 608(l)).

Claim 1 has been amended with this response to further clarify the Applicant's invention. Support for this amendment can be found throughout the specification, for example, on page 13, lines 3-13 of the originally filed application, and Figures 4-10. Claims 12 and 51 have been amended to further describe the proximal end piece. Support for the amendments to claims 12 and 51 can be found in the claims as originally filed, as well as in the originally filed specification, Figures 1A-1C, and pages 11, lines 2 – 19. Claims 54 and 56-57 have been amended to correct antecedent basis, based on amendments made to the claims in this communication. Applicant contends that no new matter has been added in making these amendments.

In a separate petition for extension of time, Applicant has requested and paid the \$510.00 small entity fee for securing a three-month extension of time for response to this Action. Should any further fees related to this document be deemed necessary, Applicant authorizes the Commissioner to deduct any additional fees as required under 37 C.F.R. §§ 1.16 to 1.21 from Locke Liddell & Sapp LLP Deposit Account No. 12-1322, referencing matter number 022471-0001US.

#### **I. Claim objections**

Claims 6 and 55 were objected to as allegedly being entirely functional and not further limiting the structure of the device as claimed, and are drawn only to the use of the device.

Claims 6 and 55 have been cancelled herein. Consequently, Applicant believes these objections to be moot.

#### **II. Objection to the specification**

The specification is objected to as allegedly failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner requests correction of the following, both of which are allegedly not included in the descriptive portion of the specification: (1) “the loading of the catheter into the epidural dispenser system is performed mechanically” in claim 17; and (2) “the loading of the catheter into the epidural dispenser system is performed through an automated process” in claim 18.

Applicant has amended the specification herein to correct the informalities relating to improper antecedent basis for claimed subject matter, as pointed out by the Examiner. The specification is now believed to be in compliant form.

The Abstract of the disclosure is objected to because 37 C.F.R. § 1.72 states that the abstract in an application filed under 35 U.S.C. § 111 may not exceed 150 words in length. The Examiner therefore required correction of the Abstract.

With this communication, the Abstract of the present application has been amended so as to bring it into compliance with 37 C.F.R. § 1.72. Applicant believes that this objection is now moot.

### **III. Rejection under 35 U.S.C. § 102**

Claims 1-2, 6-8, 10-12, 15, 51-53 and 55-57 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,159,022 to Pevsner (hereinafter "Pevsner"). For the convenience of the Examiner and clarity of purpose, Applicant has reprinted the substance of the Office Action in *10-point bolded and italicized font*. Applicant's arguments immediately follow in regular font.

*1. Regarding claims 1, 11, 15, 52 and 56, Pevsner discloses a catheter delivery system that includes a delivery housing (21) with a single cavity (inside of 53) that has at least one cylindrical and conical sidewall (53) having a proximal end (at # 59) and a distal end (65), the distal end being connected to a distal end piece (67), thereby defining the single inner cavity. See Figure 4. The distal end piece defines the upper border of the inner cavity. See figure 4. The distal end piece includes a dispensing aperture (aperture in 67) such that a loaded catheter (13) in the inner cavity can be extracted from the inner cavity through the dispensing aperture. See figure 1 and 3:60-4:6. The dispenser including the dispensing aperture is considered made of semi-rigid material. Even though Pevsner does not disclose the type of material the device is made from, all material has some degree of rigidity (depending on the reference point or value) and is therefore semi-rigid. The term semi-rigid is a relative term and without a reference point or reference value the term semi-rigid is a broad limitation that is met by any material.*

Applicant respectfully traverses the rejection of claims 1, 11, 15, 52 and 56. For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988).

Pevsner does not teach, show, or suggest every element of the presently claimed invention. Pevsner teaches an apparatus and method for the insertion of a catheter into a vein of a patient by a catheter delivery system using a pressure mechanism for delivery of the catheter. No mention or suggestion is made by Pevsner to deliver a catheter to a body of a patient in a manual manner. Further, Pevsner teaches a catheter delivery system which includes a proximal flushing hub/cannula-control fitting (14), in combination with a hollow delivery housing (21) (column 2, lines 33-36; emphasis added). As shown in Figure 4, the cannula delivery housing (21) includes a main housing (53), right/distal end (65), and a mounting protrusion (67) having a passageway therethrough. The mounting protrusion (67) is adapted to pass through a hole in a lower portion of a spring clamp (71), and attaches to an adapter (such as a Touhy-Borst adaptor, 75), which serves to attach the mounting protrusion (67) to a catheterizing tube (11). No mention or suggestion is made by Pevsner of having a dispensing aperture/hole for extracting a loaded catheter from the inner cavity of the system, as recited in independent claims 1 and 11.

The present invention describes an apparatus and method for manually delivery a catheter to a patient's body, such that contamination of the catheter is minimized or prevented. The system specifically comprises a sidewall (2) defining an inner cavity (5) containing a catheter, the system having a distal end piece (4) defining the upper border of the inner cavity. As shown and described in Figures 1B and 1D, for example, as well as within the text of the specification, there is a dispenser aperture (6) on the distal end piece, which allows the catheter to be extracted

from the inner cavity (5) (see also, page 11, line 29-page 12, line 11). This dispenser aperture (6) is a hole/opening in the top portion of distal end piece (4).

Applicant contends that dispenser aperture (6) in Applicant's present invention is not equivalent to the mounting protrusion (67) of Pevsner which is adapted to attached to an adaptor for attaching protrusion (67) to a catheter. Furthermore, in stark contrast to Applicant's invention wherein the catheter is extracted (i.e., manually) from the inner cavity of the dispenser *via* aperture (6), Pevsner specifically describes the pressure-mechanism operation of his system which relies upon protrusion (67). As recited by Pevnsner, "Once the cannula 13 is almost fully gathered in the cannula delivery housing 21, ...the mounting protrusion 67 is mounted onto the Touhy-Borst adaptor 75...fluid is applied under pressure from syringe 87 to drive the catheter 13 into the blood vessel through the catheterizing tube 11..." (column 3, line 60 – column 4, line 6). Clearly, Applicant's aperture/hole (6) is not equivalent to the mounting protrusion (67) of Pevsner.

As such, because independent claims 1 and 11 are each directed to an epidural catheter system and a method of preventing contamination of an epidural catheter, respectively, which include a dispensing aperture in the distal end piece so that a load catheter in the inner cavity of the dispenser system can be extracted through the aperture, and Applicant has found no disclosure or teaching in Pevsner of a dispensing aperture that has the specific structure or function as recited by claims 1 and 11, reconsideration of this rejection in light of these arguments is appreciated.

Regarding claims 15, 52, and 56, these claims are dependent upon independent claims 11 and 51, both of which are believed to be distinguishable and allowable regarding Pevsner.

Consequently, it is believed that these claims are deemed allowable by depending upon allowable independent claims.

Applicant respectfully requests that the rejections of claims 15, 52 and 56 under 35 U.S.C. § 102 be withdrawn.

*2. Regarding claims 2, 12, 51 and 53, the sidewall (53) of the delivery housing (21) is attached to a proximal end piece (55) which further defines the inner cavity. See figure 1. The proximal end piece defines a loading aperture (hole in cap see 3:5) such that the catheter (13) may be loaded or adjusted into the inner cavity through the loading aperture. See figure 4 and 3:30-45.*

Applicant respectfully traverses this rejection. Pevsner does not teach, show, or suggest every element of the presently claimed invention. Pevsner teaches a pressure mechanism-based catheter delivery system, as described above, which includes a delivery housing (21) having a main housing (53), a conical shaped-end (65), a mounting protrusion (67), and a circular cap (55) at the proximal end. The cap (55) has a hole therethrough at which the adapter (51) is mounted, as well as a portion (57) that is of reduced diameter to fit into opening (59) of the main housing (53). However, no mention or suggestion is made by Pevsner of the use of a proximal end piece which simultaneously further defines the inner cavity, and defines a loading aperture such that a catheter may be loaded or adjusted into the inner cavity of the dispenser system.

As recited above, Applicant's present invention is directed to an epidural catheter dispenser system comprising a sidewall (2), a distal end piece (4) having dispenser aperture (6), and proximal end piece (3), which simultaneously defines the inner cavity (5) of the system, and allows a catheter to be loaded and/or adjusted in the dispenser's inner cavity (5) through a loading aperture (7) located and defined on the proximal end piece (3). [See, Figure 1D; page

11, line 29-page 12, line 5]. Loading aperture (7) of the Applicant's present invention is not equivalent to a hole in Pevsner's circular cap (55) wherein adaptor (51) is mounted so as to form an attachment point for the cannula-control fitting (14) via hub (49), the cannula-control fitting being an integral part of Pevsner's system. Further, the use of adapter (51) in Pevsner's cap (55) does not allow for adjustment of the catheter within the inner chamber of the system via an aperture.

As such, because independent claim 51 is directed to an epidural catheter dispenser system which includes a proximal end piece connected to the proximal end of the sidewall of the system, wherein the proximal end simultaneously further defines the inner cavity of the system and defines a loading aperture such that a catheter can be loaded into or adjusted in the inner cavity through the loading aperture, and Applicant has found no disclosure or teaching of such a proximal end having the specific structure or functions recited by claim 51, reconsideration of this rejection in light of these arguments is appreciated.

Further, claims 2 and 12 are dependent upon independent claims 1 and 11, respectively, which have been distinguished above regarding Pevsner. Consequently, these claims are believed to be allowable by depending on allowable independent claims.

***3. Regarding claims 6 and 55, the dispenser is capable of being positioned in either hand of a user such that the distal end is directed toward the user's thumb and index finger so that the catheter contained within the inner cavity may be completely extracted through the dispensing aperture. Due to the amount of functional language in these two claims, the examiner reminds applicant that functional language is given limited patentable weight. As long as a prior art reference, while meeting the structural limitations of the claimed device, is capable of accomplishing the recited function, then the claimed device does not overcome the cited prior art.***

Claims 6 and 55 have been cancelled herein. Consequently, this rejection is now moot.

*4. Regarding claims 10 and 57, the inner cavity of the delivery housing (21) entirely confines the portion of the catheter that will enter the patient during the procedure except the portion of the catheter that is already extending from the delivery housing into the catheterizing tube 11. See figure 1 and 3:45-4:5. It is noted that "entirely confines" is being read broadly in the sense that the delivery housing sidewall is a solid structure that entirely confines the portion of the catheter that is shown in Figure 1 and the text cited above.*

Because claim 10 depends from claim 1, and claim 57 depends from claim 51, and because Applicant contends that claims 1 and 51 are patentable over Pevsner as originally submitted and as detailed above, no amendment is made herein to claims 10 or 57 in response to this rejection. Reconsideration of this rejection in light of these arguments is respectfully requested.

Applicant respectfully requests that the rejections of claims 1-2, 6-8, 10-12, 15, 51-53 and 55-57 under 35 U.S.C. § 102 be withdrawn.

#### **IV. Rejection under 35 U.S.C. § 103**

Claims 9 and 16-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 4,159,022 to Pevsner.

Applicant respectfully traverses this rejection. The independent claims, upon which claims 9 and 16-18 depend, have been distinguished above regarding Pevsner, and it is believed that these claims are deemed allowable by depending on allowable independent claims. For this and other reasons, Applicant believes this rejection to now be moot.

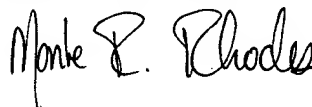
Accordingly, Applicant requests that the rejections of claims 9 and 16-18 under 35 U.S.C. § 103(a) be withdrawn.

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In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,



Monte R. Rhodes, Ph.D.  
Reg. No. 54,396  
Customer No. 26720  
AGENT FOR ASSIGNEE,  
ROBERT C. SIMPSON

Locke Liddell & Sapp LLP  
JPMorgan Chase Tower  
Suite 3400  
600 Travis Street  
Houston, TX 77002-3095  
Tel: (713) 226-1326

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